During the months of April and June 2016, the new directives on Electro-Magnetic Compatibility, Low Voltage and Radio Equipment shall come into force, placing new obligations on Manufacturers, Importers, Distributors and Authorized Representatives.

In the course of April and June 2016, the new Directives 2014/30/EU (EMC), 2014/35/EU (LVD) and 2014/53/EU (RED) will become effective. The purpose of this article is to highlight the main obligations, often new, imposed by the three important regulations on Economic Operators at which they are addressed (Manufacturers, Importers, Distributors and Authorized Representatives).

# When will the three directives come into force?

Both <u>Directive 2014/30/EU</u> (EMC) and <u>Directive 2014/35/EU</u> (LVD) will have to be implemented in national laws with effect from <u>20.04.2016</u>; as to existing supplies of non-conforming products held in stock at that date by the Manufacturer, Importer (so long as they have been cleared through custom) or Distributor, in both cases it is provided that "*Member States shall not impede the making available on the market and/or the putting into service of equipment which is in compliance with*…" the repealed directives " ...*and which was placed on the*…" EU "...*market before 20 April 2016*" (Art. 43 of Directive 2014/30/EU and Art. 25 of Directive 2014/35/EU).

With regard to <u>Directive 2014/53/EU</u> (Radio Equipment Directive or RED), it shall have to be implemented in a national law to be adopted from <u>13.06.2016</u> onwards (Art. 49): however products complaint with old regulation shall be able to be put on the EU market till <u>12.06.2017</u> included and shall be able to be freely marketed and/or put into service afterwards .

# What happens if a directive is not implemented in a national law within the given timeframe?

The European Court of Justice, as well as the Supreme Court, ruled that in the case of nonimplementation by a Member State of a European directive that from a substantive point of

view is unconditional and sufficiently precise in its terms, the following three principles shall apply:

(a) - a directive may NOT of itself impose obligations on an individual since it is aimed at the States and not to their individual citizens;

(b) - when the non-implemented Directive confers rights to individual citizens which cannot be exercised as a result of its non-implementation, the State (understood in the broadest sense and thus also National Courts, Ministries, Public Bodies, etc.) is required to "... *interpret its national law in the light of the wording and the purpose of the directive in order to achieve the result pursued by the latter*...." (ECJ case C-106/89, ruling of 13 Nov 1990);

(c) - if that interpretation is not sufficient to achieve the same scope/result pursued by the non-implemented Directive, an individual may exercise the rights deriving from the Directive against the State (but not other individuals) to seek compensation for possible damages suffered by the same as a result of its non-implementation.

However, the directives at issue are certainly 'unconditional and sufficiently precise' with the consequence that Economic Operators shall consider themselves as authorized – even though not obliged to do so – to adapt themselves even in the absence of implementation within the timeframe established by law; in fact, It goes without saying that in the case of wanting to market products imported or manufactured in Italy also in the other EU countries where the directives have already been implemented it will be necessary to adapt to their requirements.

# What is the background of these three new directives?

Towards the end of the 2000s, with Regulation (EC) No. 764/2008, Regulation (EC) No. 765/2008 and Decision No. 768/2008/EC (which has a programmatic nature), a 'New Compliance Framework for products' has been adopted, characterized by more defined responsibilities for manufacturers, greater responsibilities for importers and distributors, new procedures for market coordination and surveillance, criteria for designation of notified bodies and reorganization and revision of procedures (called 'modules') for the conformity certification and CE marking of products. All these innovations now translate into new directives which are gradually issued with the view of adapting the current procedures for

assessing and verifying the conformity of products and their accompanying documentation to these new rules and principles.

More information on this topic can be found at: <u>http://ec.europa.eu/enterprise/policies/single-</u> marketgoods/documents/internal-market-forproducts/new-legislative framework/index\_en.htm.

# What are the products covered by each directive?

## (1) The EMC Directive

With regard to Directive 2014/30/EU on Electromagnetic Compatibility (EMC), there are no particular changes and it shall always apply to any apparatus intended as "... any finished appliance or combination thereof made available on the market as a single functional unit, intended for the end-user and liable to generate electromagnetic disturbance, or the performance of which is liable to be affected by such disturbance" (Art. 3.1.2). Are excluded from the Directive all telecommunications radio equipment, apparatus used by radio amateurs, aeronautical products, custom built evaluation kits destined for professionals to be used solely at research and development facilities, and equipment which is "inherently benign", i.e. incapable of generating or contributing to electromagnetic emissions to such an extent that it would be somewhat relevant (Art. 2.2.d); are therefore excluded, for example, the following products: wires and cables; batteries and accumulators (without active electronic circuits); headphones and loudspeakers without amplification; pocket lamps without active circuits; high-voltage inductors and transformers; power factor correction capacitors; asynchronous motors; quartz watches; incandescent lamps; domestic switches with no active components, radio and television receiving antennas; sockets, plugs, terminal blocks; etc..

Finally, from the majority of the provisions of this Directive is exempt any apparatus <u>intended</u> <u>for incorporation into a particular fixed installation</u> and not otherwise made available on the market (Art. 19.1).

## (2) The LVD Directive

Also with regard to Directive 2014/35/EU (LVD), the list of covered products is fundamentally the same: "*electrical equipment designed for use with a voltage rating of between 50 and 1 000 V for alternating current and between 75 and 1 500 V for direct current*" (Art.

1), with the exclusion (already foreseen) of the following equipment and phenomena: electrical equipment intended for use in environments exposed to the risk of explosion, or for radiology and medical purposes; electrical parts for goods and passenger lifts; electricity meters; power outlets (sockets and plugs) for domestic use; electric circuits controllers; radio-electrical interference; special electrical equipment for use on ships, aircraft or railways.

Are now also excluded the 'custom built evaluation kits destined for professionals to be used solely at research and development facilities' (Annex II).

### (3) The RED Directive

As to <u>Directive 2014/53/EU</u> on Radio Equipment (RED), unlike the previous Directive 1999/5/EC on Radio Equipment and Telecommunications Terminal Equipment (R&TTE), it does no longer cover wire/fixed-line telephones or any equipment not relying on radio frequencies. In fact, the new Directive now only covers electrical and electronic equipment which intentionally emits and/or receives radio waves for the purpose of radio communication and/or radiodetermination (including equipment that, for this purpose, must be completed with an accessory, such as an antenna) (Art. 2.1.1; Annex I). The new Directive includes also radio equipment "affected by a low level of compliance": these types of equipment, to be identified with specific regulations or other delegated acts adopted by the Commission, must be registered by manufacturers within a central electronic system, which shall be made available by the Commission (Art. 5).

Are excluded the following products: - radio equipment used exclusively for activities concerning public security, defence, state security or public welfare; - amateur radio kits; - marine equipment; - airborne products, parts and appliances (regulated under Art. 3 of Regulation (EC) No. 216/2008); - custom built evaluation kits destined for professionals to be used solely at research and development facilities.

Finally, it should be noted that receive-only equipment (including devices, radio and TVs) are covered only by the RED Directive and not by the EMC Directive; moreover, the safety limits (voltage limits) provided by the LVD Directive do not apply to radio equipment.

The frequency spectrum falling under the scope of the RED Directive has now no limitations (previously it covered the range from 9 kHz up to 3000 GHz).

### What are the main changes introduced?

For the purposes of this article, but also in general terms, the main changes introduced by the three regulations examined here is the definition and division of responsibilities among the Manufacturers, their Authorized Representatives, the Importers and in particular the <u>Distributors</u> who are called on to collaborate with each other throughout the life of the product, even after its placing on the market: under previous directives, the responsibilities for other operators other than Manufacturers had to be construed on the basis of the general product safety regulation (Directive 2001/95/EC) and by taking into account different and often disparate sources (maxims of jurisprudence, administrative interpretations, sectoral rules); moreover, the collaboration between the various actors in the distribution chain mentioned above was not previously defined.

All the above also implies, as we shall see later, <u>new obligations</u> regarding labelling, marking and the documentation that must accompany the products, including monitoring their preservation, use and proper functionality for users.

In addition, also a new and more definite relevance of the Authorized Representative must be highlighted, which will be discussed further below.

## To which economic operators are the three directives addressed?

'*Manufacturer*': is any natural or legal person, whether established or not in the European Union, "... who manufactures electrical equipment or has electrical equipment designed or manufactured, and markets that equipment under his brand name or trade mark" (EMC-Dir, Art. 3.1.11; LVD-Dir, Art. 2.3; RED-Dir, Art. 1.12). By way of example, the importer TOM buys equipment in China from the supplier DICK, and introduces it for the first time in the EU market or the European Economic Area (constituted by Norway, Iceland and Liechtenstein): if the products bear the trade mark of the supplier DICK, TOM is the Importer; if they bear only the trade mark of TOM, the latter is legally the 'Manufacturer'.

'Authorized Representative': is any natural or legal person established in the EU "... who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks" (EMC-Dir, Art. 3.1.12; LVD-Dir, Art. 2.4; RED-Dir, Art. 13.1). The

appointment of an Authorized Representative is not mandatory but, if the Manufacturer is not established in the EU, under the new directives examined here this is particularly timely, as we shall see in more detail below.

'*Importer'*: is any natural or legal person established in the EU "... *who places on the Union market* ..." and thus not necessarily on the Italian market "... *apparatus from a third country*" (EMC-Dir, Art. 3.1.13; LVD-Dir, Art. 2.5; RED-Dir, Art. 1.14). <u>Please note that</u>: a) if the Importer or Distributor of the product alters or modifies it by performing some reworking activities (except where this is merely minimal or ancillary) he becomes the 'Manufacturer' of the product and takes on all legal obligations of this economic operator; b) similarly, if the Importer, as explained above, sells the product under his own trade mark, he legally becomes the 'Manufacturer' of the same ; c) if the Importer has a product manufactured by a third party and markets it with a trade mark for which he is the licensee, in the writer's opinion he is likewise to be considered as its Manufacturer<sup>1</sup>, for the same aforementioned criterion.

'**Distributor'**: is any natural or legal person, obviously established in the EU, "... *in the supply chain, other than the manufacturer or the importer, who makes apparatus available on the market*" (EMC-Dir, Art. 3.1.14; LVD-Dir, Art. 2.6; RED-Dir, Art. 1.15).

# What obligations are placed on the Manufacturer and his Authorized Representative? And on the Importer and the Distributor?

The obligations placed on Economic Operators can be broadly divided into the following four types:

- a- Assessment/Certification of products conformity
- **b- Products traceability**
- c- Instructions and precautions for use
- d- Monitoring products conformity

The <u>Manufacturer</u> must fulfil all these obligations; the <u>Importer</u> is directly responsible for certain obligations (e.g., traceability, monitoring) and indirectly for others, in having to ensure

<sup>&</sup>lt;sup>1</sup> See again in this regard, always by reference therein, also the already mentioned EU Commission's Guide for the Toys Directive 2009/48/EC, Chapter II, Art. 2.1, point 6, p. 28

in such a case that the Manufacturer has complied with them (e.g., assessment and products conformity certification); the <u>Distributor</u> has the duty to ascertain the compliance of the Manufacturer and Importer only in relation to their formal obligations inferable from the outside (e.g., products marking, their accompanying instructions and precautions for use); the <u>Authorized Representative</u>, if appointed, is responsible for specific obligations regarding the products conformity certification and cooperation with the surveillance authorities.

	Assessment	Certification	Traceability	Instructions/ Precautions	Monitoring	Proper preservation
Manufacturer	YES	YES	YES	YES	YES	NO
Importer	NO, but verifies	NO, but verifies	YES No serial no. No contact p.	YES	YES	YES
Distributor	Must	Must	Must	Must	YES	YES
	ascertain	ascertain	ascertain	ascertain		
Auth. Rep.	NO	NO	Cooperates	NO	Cooperates	NO

Let us now examine in greater detail these obligations, including whether and to what extent each Economic Operator is involved:

# (1) ASSESSMENT OF THE CONFORMITY OF THE PRODUCT TO THE ESSENTIAL REQUIREMENTS

- The <u>Manufacturer</u> is exclusively responsible for assessing the conformity of the product before placing it on the market; this assessment must be continuously monitored and updated (EMC-Dir, Art. 7.4; LVD-Dir, Art. 6.4; RED-Dir, Art. 10.5) and cannot be delegated to the Authorized Representative. This, as the case may be and depending on the directive, can be performed with or without the intervention of a Notified Body. The Manufacturer is responsible for any civil, criminal or administrative liability for the lack of conformity and possible hazard posed by the products, nor can he be released from such responsibilities by entrusting the assessment to the authorized representative or a third party of which he makes use.

- The <u>Authorized Representative</u> has no obligations in this regard, nor can he be delegated for this purpose by the Manufacturer.

- The **Importer** must ensure that the appropriate conformity assessment procedure has been carried out by the Manufacturer (EMC-Dir, Art. 9.2; LVD-Dir, Art. 8.2; RED-Dir, Art. 12.2).

- The <u>Distributor</u> must refrain from making available on the market products which he has reason to believe lack conformity with the essential requirements set out by each directive and must inform the surveillance authorities to that effect (EMC-Dir, Art. 10.2 second para; LVD-Dir, Art. 9.2 second para; RED-Dir, Art. 13.2 second para).

# (2) <u>CONFORMITY CERTIFICATION</u>: a) PREPARATION OF TECHNICAL DOCUMENTATION; b) DECLARATION OF CONFORMITY TO BE KEPT AVAILABLE FOR 10 YEARS; c) AFFIXATION OF THE CE MARKING

- The **Manufacturer** is exclusively responsible for all these three obligations. In fact, he must prepare, before placing each product on the market: (a) the Technical Documentation (diagrams, electric schematics, technical reports, etc.) and keep it available for at least 10 years after the product has been placed on the market (it is advisable to keep such documentation even for a longer period, given that in case of an accident it may be necessary to provide proof of the lack of defectiveness of the product even after this length of time); similarly, the Manufacturer must draw up the (b) EU Declaration of Conformity in accordance with the modules specified and set out in the annexes to the three directives; the Declaration may be drawn up in a language easily understood by end-users (thus also in English) as long as the Italian version is provided to the surveillance authorities upon request. The Technical Documentation and the Declaration of Conformity must be continuously updated consistently with the unique features of each product model, with changes in the harmonized standards and/or other technical specifications (thus, a Declaration of Conformity referring to outdated EN standards exposes the Manufacturer to an administrative penalty and to the request to update the Declaration itself), and must be kept for 10 years from the date on which the apparatus was placed on the market.

The Manufacturer, before placing the product on the market, must also ensure that (c) the <u>CE marking</u> is "... affixed visibly, legibly and indelibly to the apparatus or to its data plate. Where that is not possible or not warranted on account of the nature of the apparatus, it shall be affixed to the packaging <u>and</u> to the accompanying documents" (EMC-Dir, Art. 17;

LVD-Dir, Art. 17); in the case of <u>radio equipment</u>, the CE marking must be affixed to the product or – where this is not possible – only to the packaging (RED-Dir, Art. 20) and it must be followed by the identification number of the notified body if it intervenes during the conformity procedure.

- The <u>Authorized Representative</u> is, as a rule, delegated to keep the <u>technical</u> <u>documentation</u> available in the EU but CANNOT draw it up, as such activity is reserved to the Manufacturer; the Authorized Representative is instead usually delegated <u>to issue</u>, by <u>signing it</u>, the declaration of conformity</u>. Given that the CE marking must be affixed before the product is placed on the market, it appears that such activity cannot be entrusted to the Authorized Representative, if not in the – hypothetical – case of products manufactured in the EU, at a stage prior to their placing on the market by the EU Manufacturer. The Authorized Representative has also the task of <u>interfacing with the surveillance authorities</u> and provide all the product information requested by them.

- The **Importer** must ensure that the Technical Documentation and the Declaration of Conformity have been drawn up by the Manufacturer and are available, and that the CE marking has been correcly affixed; as for equipment falling under the scope of the RED Directive he must also ensure that it is accompanied by a declaration of conformity, at least in summary form.

- The **<u>Distributor</u>** must ensure that the CE marking has been properly affixed (EMC-Dir, Art. 10.2; LVD-Dir, Art. 9.2; RED-Dir, Art. 13.2): in the case of radio equipment, the Distributor must also ensure that it meets the applicable requirements on the use of radio spectrum (at least of the Member State in which it is sold) (RED-Dir, Art. 10.2.).

# (3) <u>INFORMATION FOR TRACEABILITY</u>: a) TYPE, BATCH, SERIAL NUMBER; b) DETAILS OF THE MANUFACTURER AND ADDRESS CONTACT; c) INFORMATION ON SUPPLIER AND BUYER

- The <u>Manufacturer</u> must ensure that (a) "... radio equipment which he has placed on the market bears <u>a type, batch or serial number</u> or other element allowing its identification, or, where the size or nature of the radio equipment does not allow it, that the required information is provided on the packaging, or in a document accompanying the radio

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equipment" (EMC-Dir, Art. 7. 5; LVD-Dir, Art. 6.5; RED-Dir, Art. 10. 6). It is worth noting that according to the European Commission "... There is flexibility in this requirement, allowing for the manufacturer to choose his own philosophy for identification of an apparatus for regulatory purposes. However, the identification of the apparatus must unambiguously correlate with the declaration of conformity and the technical documentation."<sup>2</sup> Moreover, Manufacturers must (b) "... indicate on the apparatus, their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the apparatus. The address shall indicate a single point at which the Manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities". (EMC-Dir, Art. 7.6; LVD-Dir, Art. 6.6; RED-Dir, Art. 10 7).

- The <u>Authorized Representative</u> can act as the "single point of contact" of the Manufacturer, if this has been delegated to him in writing. In this case, it will be the Authorized Representative address to be shown on the product as the only point at which the Manufacturer can be contacted. Moreover, it should be noted that the mandate given to the Authorized Representative for a given apparatus must necessarily include the power to "cooperate with the competent national authorities... on any action taken to eliminate the risks posed by the apparatus" (EMC-Dir, Art. 8.2.c; LVD-Dir, Art. 7.2.c; RED-Dir, Art. 11.1.c), with the result that it seems appropriate that the address of the same – if appointed – is indeed shown as the 'single point of contact'.

- <u>Importers</u> are subject only to the obligation to indicate "... on the apparatus their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the apparatus. The contact details shall be in a language easily understood by end-users and market surveillance authorities" (EMC-Dir, Art. 9.3; LVD-Dir, Art. 8.3; RED-Dir, Art. 12.3). Thus, the apparatus must bear or (in the cases provided for) be accompanied both by the Manufacturer address and that of Importer; however, in the Importer's case, unlike the Manufacturer, it is not necessary to indicate also the "single point".

<sup>&</sup>lt;sup>2</sup> 2010 Guide for the EMC Directive 2004/108/EC

*at which the Importer can be contacted*", nor, as has been said, it is necessary to show on the product the serial number or any other element allowing its identification.

- The <u>Distributor</u>, before making apparatus available on the market, must ensure that the Manufacturer and the Importer have complied with all their traceability obligations mentioned above (EMC-Dir, Art. 10.2; LVD-Dir, Art. 9.2; RED-Dir, Art. 13.2).

- The <u>Manufacturer</u>, <u>Importer</u> and <u>Distributor</u> must be able for a period of 10 years after they have been supplied with the apparatus and for a period of 10 years after they have supplied the apparatus to indicate to the market surveillance authorities (a) any economic operator who has supplied them an apparatus and (b) any economic operator to whom they have supplied it (EMC-Dir, Art. 12; LVD-Dir, Art. 11; RED-Dir, Art. 15).

# (4) <u>INDICATIONS FOR THE PROPER AND SAFE USE OF THE PRODUCT</u>: a) OPERATING INSTRUCTIONS; b) WARNINGS AND PRECAUTIONS FOR USE

- The <u>Manufacturer</u> must accompany each apparatus with (a) <u>instructions</u> that will allow its proper use in accordance with the purposes for which it is intended and (b) <u>information on precautions for use</u>, including specific precautions that must be taken when the apparatus is assembled, maintained or used (EMC-Dir, Articles 7.7 and 18; LVD-Dir, Art. 6.7; RED-Dir, Art. 18.8). All apparatus falling within the scope of the EMC DIRECTIVE "... for which compliance with the essential requirements ... is not ensured in residential areas, must be accompanied by a clear indication of such restriction of use, where appropriate also on the packaging" (Art. 18.2). As for equipment falling under the scope of the RED DIRECTIVE, additional information must be included in the case of "... radio equipment intentionally emitting radio waves..." (Art. 10.8 second para).

In any event, both the instructions and the precautions for use must be drawn up "*in a language easily understood by consumers and other end-users*" (see EMC-Dir, Art. 9.4), i.e. in Italian in the case of Italy, as provided for in Articles 6 and 9 of the Italian Consumer Code, which is not subject to exceptions in this case.

It must be assumed that today, subject to certain conditions, the information can be provided in whole or in part **also by means of drawings, symbols or pictograms**. In fact, instructions in the form of pictograms and graphic representations which are functional to the use of the product <u>were considered equivalent to written instructions</u> in several decisions

of the European Court of Justice (*Peeters*: Cases C-369/89 of 18.06.1991 and C-85/94 of 12.10.1995; *Casino France:* Case C-366/98 of 12.09.2000) and of the European Commission (COM (93) 456 of 10.11.1993 on information to consumers, para 38). In Italy, the Ministry for Economic Development issued, at the time, a notice (Ref. No. 22769 of 09.09.2008) addressed to the Chamber of Commerce of Naples, with which it ordered the release from seizure of products on which information to the consumer were provided by means of drawings, in failing to find in such circumstance any objection for not granting their release as requested by the party concerned.

- The **<u>Authorized Representative</u>** is responsible for providing additional, supplementary or complementary information to the surveillance authorities, if requested by them.

- The <u>Importer</u> must ensure that the products are accompanied by (a) instructions and (b) information, which must be drawn up and provided by the Manufacturer (EMC-Dir, Art. 9.4; LVD-Dir, Art. 8.4; RED-Dir, Art. 12.4).

- The **Distributor**, who also in these cases is required to perform control tasks, especially formal and 'visual', must likewise ensure, "*before making equipment available on the market*" that it is accompanied by the instructions and information mentioned earlier (EMC-Dir, Art. 10.2; LVD-Dir, Art. 9.2; RED-Dir, Art. 13.2).

## (5) MONITORING PRODUCT CONFORMITY

- The <u>Manufacturer</u> must (a) take appropriate and immediate corrective measures (bring the product into conformity and, if necessary, withdraw it from the market or recall it from end-users); and (b) must furthermore cooperate with the surveillance authorities and provide them with all the information requested (EMC-Dir, Articles 7.8. and 7.9; LVD-Dir, Articles 6.8 and 6.9; RED-Dir, Articles 11.10 and 10.12).

-The <u>Authorized Representative</u> cooperates with the competent national authorities, at their request, on any action taken to eliminate the risks posed by the equipment, provided that this is included in the mandate given to him (EMC-Dir, Art. 8.2.c; LVD-Dir, Art. 7.2.c; RED-Dir, Art. 11.2.c).

- The <u>Importer</u>: (a) ensures suitable storage conditions; (b) takes appropriate and immediate corrective measures (brings the product into conformity and, if necessary, withdraw it from the market or recall it from end-users), which in the case of the LVD and

RED Directives also include: carrying out sample testing; the investigation of complaints and of non-conforming materials and maintain a register of all these findings (LVD-Dir, Art. 8.6; RED-Dir, Art. 12.6); (c) cooperates with the surveillance authorities and provide them with all the information requested; (d) keeps available for 10 years the declaration of conformity and ensures that the technical documentation, if requested by the surveillance authorities, can be made available to them, also from third parties; and (e) must furthermore cooperate with the surveillance authorities and provide them with all the information requested (EMC-Dir, Articles 9.5, 9.6, 9.7 and 9.8; LVD-Dir, Articles 8.5, 8.6, 8.7, 8.8 and 8.9; RED-Dir, Articles 12.5, 12.6, 10.7 and 10.9).

- The <u>Distributor</u>: (a) ensures suitable storage conditions; (b) takes appropriate and immediate corrective measures (i.e., brings the product into conformity and, if necessary, withdraw it from the market or recall it from end-users) and immediately informs the surveillance authorities if the equipment poses a risk; (c) cooperates with market surveillance authorities and provide them with all the information requested (EMC-Dir, Articles 10.3, 10.4 and 10.5; LVD-Dir, Articles 9.3, 9.4 and 9.5; RED-Dir, Articles 10.3, 10.4 and 10.5).

# The Authorized Representative: how is he appointed and what are his functions?

The Manufacturer, whether established or not in the EU territory, <u>may</u> appoint an Authorized Representative located in the EU, provided that:

a - the appointment is made in writing and clearly sets out his functions and powers;

b - are not delegated to him <u>any of the activities reserved to the Manufacturer</u>, such as drawing up the technical documentation, modify or manufacture the product;

c - <u>at least the three following tasks are assigned to him</u>: **(1)** keep the EU declaration of conformity and the technical documentation at the disposal of the national authorities for at least 10 years after the product has been placed on the market; **(2)** following a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product covered by the authorised representative's mandate; **(3)** cooperate with the competent national authorities,

at their request, on any action taken to eliminate the risks posed by an apparatus covered by the mandate given to him (EMC-Dir, Art. 8.2; LVD-Dir, Art. 7.2; RED-Dir, Art. 11.2). Further tasks that may be included in the written mandate entrusted to the Authorised Representative:

- affixing the CE marking;

- drawing up and signing the declaration of conformity;

- acting as national contact point or single EU contact point for the Manufacturer.

The Authorised Representative may be a professional, a consulting firm (**my law firm, for example, ensures the Authorized Representative function in having the technical and legal skills required for this purpose**), or even the same Importer or Distributor (who will however be unlikely to shoulder this burden in order to not add to their responsibilities also those of the Authorized Representative, unless it is a subsidiary or affiliated company of the Manufacturer).

It is advisable that the Importer ensures that his supplier appoints or has already appointed an Authorized Representative in the EU territory, as the timeframe for delivering the technical documentation, updated declarations of conformity and specific product information to the competent authorities and the timescale for complying with the procedures concerning products presenting a 'risk' or 'hazard' in order to ensure the safety of the market place, are fairly short and too often the Importer and, as a knock-on effect, the Distributor are left entirely alone to meet the Manufacturer's obligations, with the resultant application of the penalties foreseen by the national laws transposing the directives at issue.

Finally, it should be noted that all functions examined above and delegable to the Authorized Representative – notwithstanding his possible 'internal' advisory and technical legal assistance to the Manufacturer – are managerial and operational in nature, meaning that if a product is not in conformity or even dangerous and/or causes damage to persons or property, any administrative, civil and, where appropriate, also criminal liability shall be and remain the responsibility of the Manufacturer, the sole party legally accountable for such occurrences.

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